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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,793	06/26/2001	David J. Ecker	IBIS-0368	1490
34138	7590	10/20/2004	EXAMINER	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 10/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/891,793

**Applicant(s)**

ECKER ET AL.

**Examiner**

Ardin Marschel

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 51-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                         |                                                                                                                  |
|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                             | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>(2 copies)</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____.                                                                        |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/04 has been entered.

### **VAGUENESS AND INDEFINITENESS**

Claims 51-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the instant claims are unclear as to whether the intent is to direct the claim practice of identification of organisms with genes or generic bioagents. It is noted that both the broad "bioagent" limitation is present in claim 51 as well as the practice of gene variable regions and conserved regions which is indicative of providing characterizing information only about organisms which have such regions. Thus it is unclear whether generic bioagents are meant to be characterized which may include simple DNA, RNA, or possibly chemicals that may be utilized as bioagents. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 51 also contain this unclarity due to their dependence.

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### **PRIOR ART**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51, 63-65, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Margery et al. (P/N 6,055,487) or Coli et al. (P/N 6,018,713); taken in view of either of Muddiman et al. [Analytical Chem. 69:1543-1549 (1997)] or Muddiman et al. [Analytical Chem. 68:3705-3712 (1996)]; taken further in view of Widjojoatmodjo et al. [J. Clin. Micro. 32(12):3002-3007(1994)].

The combination of Margery et al. or Coli et al., taken in view of either of Muddiman et al.(1997) or Muddiman et al. (1996) has been summarized in the previous office action, mailed 8/26/03. This combination describes the basic invention as claimed, however, lacks a description of conserved primer amplification for identification purposes regarding specific gene regions as cited in claim 51, such as genes involved in translation, etc. Said previously cited combination of references suggests and motivates identification wherever conserved primer amplification produces characteristic

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products for identification as is set forth in the art. An example of this motivation as generally applicable for identification is given in Muddiman et al. (1996), page 3712, in the CONCLUSIONS section wherein the "general applicability of this approach" is stated in the first column, lines 12-14. Genetic variations are also suggested as determinable in Muddiman et al. (1996), page 3712, in the bridging sentence between the first and second columns. Different species of organisms are well known to correspond to genetic variations therein.

The art contains a description of the presence of conserved primer amplification regions for identification which is described in genes involved with translation in Widjoatmodjo et al. in the abstract as directed to 16S rRNA genetic sequences. 16S rRNA are present in ribosomes and clearly involved in translation in cellular processes as one of the options listed in instant claim 51.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the conserved primer amplification identification via ribosomal rRNA sequences as set forth in Widjoatmodjo et al. in the method of the combination of Margery et al. or Coli et al., taken in view of either of Muddiman et al.(1997) or Muddiman et al. (1996) which has been summarized in the previous office action, mailed 8/26/03, as motivated and suggested above to result in a reasonable expectation of success of performing the invention of the above listed instant claims.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices

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published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 15, 2004

*Ardin H. Marschel* 10/15/04  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER